

PART III: CONSUMER INFORMATION

PrLIVOSTIN®

levocabastine Nasal Spray

0.5 mg/mL as levocabastine hydrochloride

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LIVOSTIN®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

LIVOSTIN® is a prescription medication for the treatment of allergies in people 12 years of age and older. The nasal spray is for the rapid and long-lasting relief of nasal complaints, such as sneezing, runny and itchy nose associated with allergies to grass, pollen, moulds, dust or other substances.

What it does:

When LIVOSTIN® is sprayed into your nose, it helps reduce the symptoms associated with allergies such as sneezing, runny and itchy nose.

LIVOSTIN® blocks the action of histamine and relieves allergy symptoms. Histamine is a chemical released by the immune system — the body’s defence against invading substances — when the body is affected by substances that you are allergic to (allergens).

When it should not be used:

Do not use LIVOSTIN® if you are allergic to it or any of its ingredients (see **What the nonmedicinal ingredients are**). If you are not sure, talk to your doctor or pharmacist.

What the medicinal ingredient is:

levocabastine hydrochloride

What the nonmedicinal ingredients are:

benzalkonium chloride, propylene glycol, polysorbate 80, disodium phosphate, monosodium phosphate, disodium edetate, hypromellose and water.

What dosage forms it comes in:

LIVOSTIN® comes in a nasal spray. It is a sterile white suspension in plastic spray bottles containing 15 mL.

WARNINGS AND PRECAUTIONS

Before you use LIVOSTIN® talk to your doctor or pharmacist if you are:

- pregnant or planning to become pregnant
- breast-feeding
- suffering from a kidney disorder.

Except on the advice and under the supervision of your doctor, you should not use LIVOSTIN® nasal spray if you are suffering from a kidney disorder.

LIVOSTIN® usually does not affect alertness or concentration. However, should you feel drowsy, be careful while driving or operating machinery.

LIVOSTIN® is only for use in people 12 years and older.

Your doctor has prescribed this medicine for you. Do not give this medicine to anyone else.

INTERACTIONS WITH THIS MEDICATION

No interactions with other medications have been reported during clinical trials.

PROPER USE OF THIS MEDICATION

LIVOSTIN® nasal spray comes as a suspension. So **shake the bottle well** before each use. For adults and children 12 years of age and older, the usual dose is **2 sprays of LIVOSTIN® for each nostril twice a day**. If your symptoms are very bothersome, you can spray 3 or 4 times a day. Follow your doctor’s directions carefully.

1. Shake the bottle well before removing the cap.
2. Before using LIVOSTIN® nasal spray for the first time, remove the cap and squeeze the bottle once or twice until a fine spray appears in the air.
3. Blow your nose.



4. Hold the bottle as shown in the picture. Tilt your head slightly forward. Keep one nostril tightly closed and insert the nozzle into the other nostril.
5. Spray twice, while breathing in through the same nostril.
6. Repeat steps 4 and 5 for the other nostril.

Overdose:

This nasal spray is for use in your nose only, but if you accidentally drink LIVOSTIN®, you will likely feel sleepy. Drink plenty of non-alcoholic fluids to speed up the elimination of drug from your system and contact your doctor.

In case of accidental drug overdose, contact a health care practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your dose by several hours, take your next dose at your usual time. **Do not** take an extra dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- headache
- nose irritation, discomfort, pain, burning, swelling or dryness (to the skin in the nose that comes in contact with the medicine)
- nose bleed
- stuffy nose
- sinusitis (inflammation of the sinuses)
- throat pain
- cough
- nausea, fatigue, achiness
- drowsiness, dizziness
- a general feeling of being unwell
- swelling of the eyelid

If these or any other unwanted effects are severe, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very rare	abnormally fast heartbeat			✓
	Palpitations: hard, strong or irregular heart beats			✓
	Airway Constriction: difficulty breathing, shortness of breath, chest tightness			✓
	Allergic Reaction (Hypersensitivity): rash, hives, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing			✓

This is not a complete list of side effects. For any unexpected effects while taking LIVOSTIN®, contact your doctor or pharmacist.

HOW TO STORE IT

LIVOSTIN® should be stored at room temperature (15°C-30°C). LIVOSTIN® nasal spray should be kept in a safe place where children cannot reach it.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full Product Monograph go to: www.janssen.com/canada. or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by
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